

INFORMAL SECTION ROUGH DRAFT – APRIL 2005

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH RADIATION SAFETY SECTION IONIZING RADIATION RULES

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PART ~~14~~10. PARTICLE ACCELERATOR INSTALLATIONS

R325.5431. Purpose and scope.

Rule 431. (1) This part establishes procedures for the ~~licensing or registration and the use of~~ particle accelerators, ~~a classification system for particle accelerator installations and use, and radiation safety requirements for persons utilizing all types of particle accelerators except those specifically exempted from this part.~~

Simplified wording for clarity.

(2) This part applies to all ~~licensees and registrants~~ who use particle accelerators for any purpose other than those exempted under rule 432. The use of particle accelerators in the healing arts is addressed in part 14 of these regulations.

(3) In addition to the requirements of this part, all ~~licensees and registrants~~ are subject to the applicable provisions of the other parts.

R325.5432. Definitions.

Rule 432. (1) "Particle accelerator" or "accelerator", as used in this part, means a radiation machine designed for or capable of accelerating electrically charged particles, such as electrons, protons or deuterons, with an electrical potential in excess of 1 MeV. Radiation machines designed and used exclusively for the production of electron beams or x-radiation for any of the following purposes ~~except those capable of producing radioactive material in excess of exempt quantities listed in schedule B of rule 147~~ are excluded from this definition:

- (a)** The diagnosis or treatment of patients.
- (b)** Industrial radiography.
- (c)** Examination of the microscopic structure of materials.
- (d)** Manufacturing process control.

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(e) Research and development.

(f) Demonstration of scientific principles for educational purposes.

(2) "Radiation protection supervisor" means 1 specific individual appointed by the licensee or registrant who has been delegated the responsibility and authority to govern the operation of the accelerator in such a manner as to comply with the provisions of this part and parts 51 through 4 and to enforce any written procedures approved by the department.

LICENSE OR REGISTRATION

R325.5435. General provisions.

Rule 435. (1) Except as otherwise provided in these rules, a person shall not ~~manufacture, produce, own, receive, acquire, possess, use, transport, transfer or dispose of a research, production, processing or treatment particle accelerator capable of producing radioactive material in excess of exempt quantities listed in schedule B of rule 147 unless authorized in a specific license registered issued pursuant to part 2 of these rules.~~

Changed according to suggested state regulation I.2.

(2) ~~Each person having a particle accelerator subject to this part shall comply with the registration requirements of part 4 unless the particle accelerator is licensed by a specific license issued pursuant to part 2.~~ In addition to the requirements of part 4 of these regulations, a registration application for the use of a particle accelerator will be approved only if the department determines that:

(a) The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this part and part 4 of these regulations in such a manner as to minimize danger to public health and safety or property.

(b) The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property.

(c) The issuance of the registration will not be inimical to the health and safety of the public.

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(d) The applicant has appointed a radiation protection supervisor.

(e) The applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses.

(f) The applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the department.

(g) The applicant has an adequate training program for operators of particle accelerators.

~~[Note: The requirements of this rule that pertain to radiation machine registration, licensing, or compliance are under the purview of the Michigan Department of Consumer & Industry Services.]~~

Modified according to applicable parts of suggested state regulation I.3.

(3) For the purpose of registering and approving mobile or portable particle accelerators intended for limited use at temporary job site locations, the registrant must limit operations to no longer than 30 days unless written authorization is granted by the department. This authorization, in the form of a specific registration condition, may be granted by the department for operations longer than 30 days but not longer than 6 months at any 1 location when an undue and unnecessary hardship may result from the 30 day limitation. Written request by the applicant for this authorization is required and shall describe the hardship involved as well as provide written assurance of compliance with these rules. This assurance shall be in the form of satisfactory written operating procedures.

Subrule 3 is taken from the requirements for class D operations which are removed below.

(4) Registration of particle accelerators does not authorize production and/or distribution of radioactive materials which may be regulated by the Department of Environmental Quality (DEQ). Such materials may be registered separately by the DEQ.

Subrule 4 is added to clarify the distinction in regulation between radiation machines and radioactive materials currently in Michigan – which particle accelerators installations could involve both.

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(5) Human use of particle accelerators is addressed in part 14 – radiation therapy.

Added to clarify the distinction between the 2 parts.

CLASSIFICATION

~~R325.5437. Class enumeration.~~

~~Rule 437. (1) For the purpose of licensing or registering and approving particle accelerator installations they shall be classified as class AA, class A, class B, or class C.~~

~~(2) For the purpose of licensing or registering and approving mobile or portable particle accelerators intended for limited use at temporary job site locations this use shall be classified as class D operation.~~

~~R325.5438. Class AA installations.~~

~~Rule 438. (1) In class AA installations the accelerator and objects exposed thereto shall be contained within a permanent enclosure.~~

~~(2) The enclosure shall be constructed such that the radiation exposure dose equivalent rate as measured in air at a distance of 5 centimeters from any accessible point on the external surface shall not exceed 2 millirems per hour under conditions of maximum radiation output permitted by the design or operating characteristics of the accelerator.~~

~~(3) Mechanical or electrical limiters shall limit movement or alignment of the accelerated beam within the enclosure if necessary to comply with subrule (2).~~

~~(4) A personnel barrier posted in accord with rules 224 to 231 restricting access to the roof of the enclosure shall meet the requirement of subrule (2).~~

~~(5) Reliable interlocks shall be provided which will prevent anyone from opening the enclosure while the accelerator is in operation or which will terminate machine operation should anyone open the enclosure. These interlocks shall comply with rule 448.~~

~~(6) Enclosures of sufficient size to permit human occupancy shall be provided with visible or audible signals or both within the enclosure which are activated a minimum of 5 seconds before accelerator operation. Persons shall at all times be able to escape from within the enclosure.~~

~~(7) An individual shall not be permitted to remain within the enclosure while the accelerator is in operation except as a human patient undergoing radiation treatment.~~

~~(8) Protective enclosures and equipment shall be kept in good repair.~~

~~(9) Electron beam welders shall meet class AA requirements.~~

~~(10) Class AA approval permits unlimited use at maximum capacity.~~

~~R325.5439. Class A installations.~~

~~Rule 439. (1) Class A installations shall comply with all requirements of rule 438 except for a permissible exposure dose equivalent rate of 7 millirems per hour at any accessible external point.~~

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~~(2) A personnel monitoring device, such as a film badge dosimeter or thermoluminescent dosimeter, shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.~~

~~(3) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.~~

~~(4) Class A approval permits unlimited use at maximum capacity.~~

~~R325.5440. Class B installations.~~

~~Rule 440. (1)~~ ~~Class B installations shall comply with all requirements of rule 439.~~

~~(2) Accelerator beam current and potential controls shall be mechanically or electrically limited so as not to exceed the normal operating conditions as specified by the applicant at the time of application for specific license or registration.~~

~~(3) Class B approval permits unlimited use under normal operating conditions as specified by subrule (2).~~

~~R325.5441. Class C installations.~~

~~Rule 441. (1)~~ ~~Class C installations shall comply with all requirements of rule 439 except for a permissible exposure dose equivalent rate of 50 millirems per hour at any accessible external point.~~

~~(2) The maximum weekly accelerator beam on time shall be established by the department under the conditions specified by the registrant at the time of application for specific license or registration.~~

~~(3) Warning signs shall be posted in those areas outside the enclosure in which the radiation exposure dose equivalent rate in air at any accessible external point exceeds 2 millirems per hour under conditions of maximum radiation output permitted by the design or limited operating characteristics of the accelerator.~~

~~(4) A daily usage log shall be maintained to record machine operation. The record shall be available at the accelerator site for examination by the department.~~

~~R325.5442. Class D operations.~~

~~Rule 442. (1)~~ ~~Particle accelerator operations conducted under conditions not meeting the provisions and requirements of rules 438 to 441 shall be classified as class D operations and shall not be operated longer than 30 days unless written authorization is granted by the department.~~

~~(2) Written authorization in the form of a specific license or registration condition may be granted by the department for class D operations longer than 30 days but not longer than 6 months at any 1 location when an undue and unnecessary hardship may result from the 30-day limitation. Written request by the applicant for this authorization is required and shall describe the hardship involved as well as provide written assurance of compliance with the requirements of these rules for class D operation. This assurance shall be in the form of satisfactory written procedures which shall be approved by the department before the issuance of a specific license or certificate of registration.~~

The classification system is being eliminated to simplify the rules and be consistent with the suggested state regulations.

SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

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R325.5445. General provisions.

Rule 445. (1) Rules 445 to 455-6 establish radiation safety requirements for the use of particle accelerators. The provisions of such rules are in addition to, and not in substitution for, other applicable provisions of these rules.

(2) A ~~licensee or~~ registrant shall be responsible for assuring that all requirements of this part are met.

R325.5446. Limitations.

Rule 446. (1) A ~~licensee or~~ registrant shall not permit an individual to act as an accelerator operator until the individual:

(a) Has been instructed in radiation safety and has demonstrated an understanding thereof.

(b) Has received copies of and instruction in this part and the applicable requirements of part 54, pertinent ~~license or~~ registration conditions, and the ~~licensee's or~~ registrant's operating and emergency procedures, and has demonstrated understanding thereof.

(c) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in his assignment.

(2) The radiation safety committee or the radiation protection supervisor shall have the authority to terminate the operations ~~at an accelerator facility or of a class D operation~~ at a particle accelerator facility if this action is deemed necessary to protect health and minimize danger to public health and safety or property.

Changed to improve clarity and include all accelerator use.

R325.5447. Shielding.

Rule 447. (1) The design and shielding specifications for an accelerator shall be submitted and approved before ~~issuance of a license or~~ registration by the department. After construction and installation the

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radiation safety of the installation shall be established by a protection survey conducted in accord with rule 221. A written report of the initial survey shall be submitted to the department and approved in writing before continued operation of the accelerator.

(2) Each accelerator installation shall be provided with such primary or secondary barriers as are necessary to assure compliance with ~~rules 203, 205 and 211~~ the dose limit requirements in part 4 of these regulations.

R325.5448. Accelerator controls and interlock systems.

Rule 448. (1) Instrumentation, readouts and controls on the accelerator control console shall be clearly identified and easily discernible.

~~(2) All entrances or openings~~ (2) Each entrance or opening into a target room or other high radiation area shall be provided with a safety interlocks that shuts down the machine under conditions of barrier penetration.

Changed to suggested state regulation wording.

(3) When ~~an a~~ a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped, and lastly at the main control console.

(4) A safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.

(5) A safety interlock shall be fail safe, i.e., designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

(6) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. This cutoff switch shall include a manual reset so that the accelerator cannot be

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restarted from the accelerator control console without resetting the cutoff switch.

R325.5449. Warning devices.

Rule 449. (1) Locations designated as high radiation areas, and entrances to these locations shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

(2) ~~Except in installations designed for human exposure, e~~Each high radiation area shall have an audible warning device which shall be activated for 15 seconds before the possible creation of a high radiation area. This warning device shall be clearly discernible in all high radiation areas and all radiation areas.

Subrules 1 and 2 are changed to reflect current suggested state regulations.

(3) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with ~~rules 224 to 233~~ part 4 of these regulations.

R325.5450. Equipment control and operations.

Rule 450. (1) A particle accelerator shall not be left unattended without locking the control panel in some manner which will prevent its use by unauthorized persons.

(2) A building housing a fixed particle accelerator shall not be left unattended without locking the building or portions thereof in some manner which will prevent unauthorized entry into the control room or target room, ~~or any access to areas which may contain induced radioactivity resulting from accelerator operation.~~

Radioactivity induced by accelerator use is under the MDEQ now due to executive orders 96-1 and 2.

(3) A mobile or portable particle accelerator shall not be left unattended without locking the room or building in which it is housed in some manner which will prevent its removal by unauthorized persons.

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(4) Access to or possession of keys or combinations used to comply with the requirements of subrules (1) to (3) shall be limited to specific authorized persons approved by the radiation protection supervisor.

(5) Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency or during periodic testing of the interlock system.

(6) All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed 3 months. Results of these tests shall be maintained for inspection by the department at the accelerator installation.

(7) Electrical circuit diagrams of the accelerator, and the associated safety interlock systems, shall be kept current and maintained for inspection by the department and shall be available to the operator on file at each accelerator installation facility.

Wording changed to parallel current suggested state regulations.

(8) If for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(a) Authorized by the radiation protection supervisor pursuant to rule 244 part 4 of these regulations.

(b) Recorded in a permanent log and a notice posted at the accelerator control console.

(c) Terminated as soon as possible.

(9) A copy of the operating and the emergency procedures shall be maintained at the accelerator control panel.

R325.5452. Radiation surveys.

Rule 452. (1) A licensee or registrant shall maintain at each accelerator installation ~~or class-D~~

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operation-appropriate calibrated and operable portable radiation monitoring instruments to make physical radiation surveys as required by this part and part 54.

(2) These instruments shall be capable by design, calibration and operation of measuring the intensity of the various types and energies of radiation produced by the accelerator. These instruments shall be tested for proper operation at the beginning of each day they are to be used and calibrated at intervals not to exceed 3 months 1 year, and after each servicing or repair.

Calibration interval is longer according to suggested state regulations due to improved monitoring equipment stability.

(3) During repair or calibration of a radiation monitoring instrument, a spare calibrated and operable instrument shall be provided or accelerator operations which require the instrument shall be terminated until required instrumentation is available.

(4) A radiation protection survey shall be performed and documented in accord with rule 221 part 4 of these regulations when changes have been made in shielding, operation, equipment or occupancy of adjacent areas, and periodically to check for unknown changes and malfunctioning equipment.

(5) Radiation levels in all accessible high radiation areas shall be continuously monitored ~~except in installations designed for human exposure.~~ The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a remote and local readout with visual or audible alarms or both at the control panel and at the monitoring stations.

Modified wording parallel to current suggested state regulations.

(6) All area monitors shall be calibrated at ~~established periodic intervals approved by the department~~ intervals not to exceed 1 year and after each servicing or repair.

Modified according to suggested state regulations.

~~(7) Whenever applicable, periodic surveys shall be made to determine the amount of airborne radioactivity present in areas of airborne hazards.~~

~~(8) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination~~

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~~in target and other pertinent areas.~~

~~(9) All area surveys shall be made in accordance with the written procedures established by a health physics consultant or the radiation protection supervisor of the accelerator facility and approved by the department.~~

Radioactive material control is under the MDEQ now due to executive orders 96-1 and 2.

~~(10)(7)~~ Records of all radiation protection surveys, calibration results, and instrumentation tests ~~and smear results~~ shall be kept current and on file at each accelerator facility.

~~[Note: The requirements of this rule that pertain to radiation machine registration, licensing, or compliance are under the purview of the Michigan Department of Consumer & Industry Services.]~~

R325.5455. Special precautions.

Rule 455. A licensee or registrant shall not permit dismantling, repair or servicing of any portion of the accelerator or changing of target materials by any persons unless such persons have been approved for such activity by the radiation protection supervisor. The radiation protection supervisor shall determine that such persons are:

(a) Qualified by training or experience to conduct such activities safely with respect to potential radiation hazards.

~~(b) Knowledgeable regarding the potential hazards of induced radioactivity.~~

~~(c)(b)~~ Provided with appropriate monitoring instruments and dosimeters.

~~(d)(c)~~ Informed of any special procedures or precautions necessary to protect themselves and other from radiation exposure or spread of contamination.

Reference to radioactive materials removed – now regulated by DEQ.

R325.5456. Personnel Monitoring.

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Rule 456. (1) A personnel monitoring device, such as a film badge dosimeter or thermoluminescent dosimeter, shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

(2) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.

Rule 456 is created here to include these requirements from the deleted Class A section for all users of accelerators.